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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,787	10/01/2003	Hiddenobu Yaku	061352-0045	3667

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MCDERMOTT WILL & EMERY LLP
600 13TH STREET, N.W.
WASHINGTON, DC 20005-3096

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,787	YAKU ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I (claims 1-12, and 19-27), in the reply filed on July 8, 2005 is acknowledged. Applicants' response neither indicated whether the election is without traverse or with traverse nor provided any arguments for traversal. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status

2. Claims 1-12 and 19-27 are considered for examination. Claims 13-18, 28-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups. This is made FINAL.

Information Disclosure Statement

3. The Information Disclosure Statement filed on October 1, 2003 has been entered and considered.

Priority

4. This application filed on October 1, 2003 claims foreign priority to Japanese patent application JAPAN 2002-288837 filed on October 1, 2002.

Objection to the Specification

5. The specification is objected because of the following informalities:

(i) The instant specification claims a foreign priority to a Japanese patent application JAPAN 2002-288837 filed on October 1, 2002. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

(ii) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

The instant application recites sequences that are not identified by SEQ ID No. (see at least Figure 14, and Fig. 17 recite a nucleic acid sequence with more than 10 nucleotides, which is not identified by SEQ ID NO).

(iii) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see at least page 6, 14-17). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

(iv) the title of the specification is too lengthy.

Appropriate correction is required.

Objection to the abstract of the disclosure

6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because abstract contains more than 150 words. Correction is required. See MPEP § 608.01(b).

Informalities

7. The instant application is reviewed for informalities and it is noted that in claims 1-2 and 19, “the step” is repeatedly used. Examiner notes that the preamble of the claims recite method comprising the following steps and recitation of each step with “the step” does not limit the scope of the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nyren et al. (WO 98/13523) in view of Zhen et al. (J Biol. Chem., Vol. 272 (35), pp 22340-22348, 1997).

Nyren et al. teach a method of claims 1-2, 8, and 19, of detecting an extension reaction and identifying a base at a target nucleic acid sequence (discriminating a base type) or detecting

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a base sequence of a target nucleic acid, wherein Nyren et al. disclose that said method comprises

(a) preparing a sample solution containing a nucleic acid, a primer having a base sequence that is complementary to said target nucleic acid and a nucleotide (see page 3, line 1-9 of paragraph 2, page 32, line 2-8 of claim 1);

(b) allowing said sample solution to stand under conditions that cause said extension reaction and producing pyrophosphate (PPi) when said extension is caused (see page 3, line 1-13 of paragraph 2, page 32, line 1-9 of claim 1);

(d and e) measuring the release of pyrophosphate and detecting said extension (see page 3, line 7-13, page 32, line 5-11 of claim 1, and claim 2, indicating PPi is measured enzymatically and thereby extension product is detected).

With regard to claims 1-2, 5, and 19 Nyren et al also teach that said method detects extension products and identifies single base polymorphisms (base discrimination) and base sequence of the target nucleic acid (see page 12, paragraph 2, page 13, paragraphs 1-2, indicating the detection of base discrimination in heterozygous material and detection of base sequence of the target nucleic acid);

With regard to claim 7, Nyren et al. teach use of two different nucleotides to discriminate a base type (see page 3, line 1-13 of paragraph 2, page 32, 5-22 of claim 1, indicating two types of nucleotides used to discriminate base type);

With regard to claims 11, and 26, Nyren et al. teach that the PPi release is measured electrically (page 4, paragraphs 3-4, indicating the use of light sensitive device, luminometer);

With regard to claim 12, and 27, Nyren et al. teach that said extension reaction is performed using polymerase chain reaction (PCR) (see page 3, line 1-10, page 32, claim 1).

However, Nyren et al. did not specifically teach contacting sample solution with a permeable membrane having H^+ pyrophosphatase which hydrolyses pyrophosphate released during extension reaction and measuring the H^+ concentration either in solution on the front face of the membrane or in the solution at the back face of the membrane.

Zhen et al. teach a method for measuring pyrophosphate of claims 1-2, 3-4, 6, 8-10, 19-25, wherein Zhen et al. teach that said measuring includes the use of membrane associated H^+ pyrophosphatase and measuring the release of H^+ PPi concentration differences in pH gradient solutions (see page 22342, paragraph 2).

With regard to claims 9-10, and 24-25, Zhen also teach the use of a pH sensitive pigment, acridine orange (page 22342, line 1-3 of paragraph 2).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of detecting extension product or base sequence based on PPi release as disclosed by Nyren et al. with the step of including membrane associated H^+ pyrophosphatase to measure PPi release as disclosed by Zhen et al for the purpose of developing a sensitive method for a stably detecting base extension reaction of a target nucleic acid. An ordinary person skill in the art would have been motivated to combine the method taught by the Nyren et al. with the inclusion of membrane associated H^+ pyrophosphatase to achieve expected advantage of developing a sensitive method for detecting base sequence of a target nucleic acid. The ordinary artisan would have a reasonable expectation of success that the inclusion of said membrane associated H^+ pyrophosphatase would result in a sensitive

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measurement of PPi released during extension reaction because Zhen et al. explicitly taught the use of membrane associated H⁺ pyrophosphatase in measuring the differences in PPi hydrolysis and H⁺ translocation of mutant and wild type (see page 22340; col. 1, paragraph 1 (abstract or summary)) and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 19-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-9, 14-19 of copending Application No. 10/727,664 (Pub No. US 2004/0197803). Although the conflicting claims are not identical, they are not patentably distinct from each other because an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-12 and 19-27 are generic to all that is recited in claim 1 in combination with claims 3-9, 14-15 of the co-pending application. That is, the claim 1 in combination with claims 3-9, and 14-15 of the co-pending application fall entirely within the scope of claims 1-12, and 19-27 or in other words, claims 1-12 and 19-27 are anticipated by the claim 1 in combination with claims 3-9, 14-19 of the co-pending application. Specifically the method of steps (a) through (e) disclosing a method of detecting extension or base type or base sequence in a target nucleic acid comprising a primer extension reaction and measuring the release of pyrophosphate and measuring H^+ concentration using a permeable membrane having H^+ pyrophosphatase and detecting extension product based on the measurement of H^+ concentration of the claim 1 in combination with 2-9, 14-19 of the claim 23 of the co-pending application are within the scope of the instant claims 1-12 and 19-27. Further the instant claims 9-11, and 24-26 are generic to all that is recited in the claims 16-19 of the co-pending application, in other words, the instant claims 9-11, and 24-26 are anticipated by claims 16-19, that is claims 16-19 of the co-pending application fall entirely within the scope of the instant claims 9-11 and 24-26. Thus the instant claims encompass the claims in the co-pending application and are related as genus and species, and are coextensive in scope.

The courts have stated that a genus is obvious in view of the teachings of a species. see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed.Cir. 1989). Therefore the instantly claimed method is obvious over the claims in the co-pending application.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

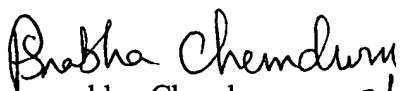
Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru
Patent Examiner
Art Unit 1637
9/19/05